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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,818	08/13/2001	Leland F. Wilson	9050-0013.24	9897

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EXAMINER	
CHISM, BILLY D	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/929,818	WILSON ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *16-19 and 29-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 20-28* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-28, in the response filed 23 January 2004 is acknowledged. The Examiner acknowledges the Applicants' election of Group I claims 1-28 for the purpose of this action. Furthermore, the Applicants have indicated that the Examiner failed to include SEQ ID NO: 1 in the restriction. The Examiner acknowledges the deficiency in the previous restriction and per a telephone conversation with Applicants' representative, the Examiner extended the restriction to include SEQ ID NO: 1 of the application. As stated in Applicants' traversal to the restriction, Applicants elected SEQ ID NO: 1 and claims 1-28 for prosecution. The traversal is on the ground(s) that if the Examiner allowed the restriction to include SEQ ID NO: 1, Applicants would elect (as noted above), and there would not be a burden on Examiner to search the product and method claims, 1-40, insofar as the claims pertain to the elected SEQ ID NO: 1. This is not found persuasive because as demonstrated in the restriction, a search for the product does not necessarily encompass a complete search for the methods, and would present a burden on Examiner.

The requirement is still deemed proper and is therefore made FINAL.

This office action is the first action on the merits. Claims 16-19 and 29-40 are withdrawn from consideration as drawn to nonelected subject matter. Claims 1-15 and 20-28 are under consideration.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the parent application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-15 and 20-28 of this application. The current application does not

possess literal support for the claimed method of using VIP. Without literal support in the parent application, one must look for inherent support, and again the support is lacking in the specification. All applications in the claimed path of priority are drawn to a large genus of vasoactive agents and VIP agonists, but no claims or disclosure is presented for the method of using VIP.

Claim Rejections - 35 USC § 112

1. **The following is a quotation of the second paragraph of 35 U.S.C. 112:**

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 and 20-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 23-28 are rejected for the indefinite recitation of non-elected subject matter, wherein "agonists thereof and combinations thereof" were not elected.

Claim 24 is rejected for the indefinite recitation of the phrase "maintaining improving" wherein it is unclear as to which the Applicants are claiming.

Claims 2-15 and 20-22 are rejected for depending from rejected claims.

3. **The following is a quotation of the first paragraph of 35 U.S.C. 112:**

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 25-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In re Wands, 8 USPQ2d 1400 (1988), discloses the factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph. They are:

1. the nature of the invention: The nature of the invention is of a pharmaceutical for the treatment of vaginal atrophy and vaginal pain during sexual intercourse, or to keep from happening.

2. the breadth of the claims: In the instant case, applicants are claiming a composition that is an agent for "preventing" vaginal atrophy and vaginal pain during sexual intercourse.

3. the state of the prior art: The state of the art does not teach the absolute prevention of vaginal atrophy and vaginal pain during sexual intercourse, merely that the symptoms of the dysfunctions, such as muscle tone and tissue health, and dyspareunia (specification page 42, line 18-22), are may be treated.

4. the predictability or lack thereof in the art: Any claim to the prevention of vaginal atrophy and vaginal pain during sexual intercourse is highly unpredictable given the current state of the art.

5. the amount of direction or guidance present and the presence or absence of working example: Applicants state that the invention may be used in the prevention of occurrence of symptoms (specification page 10, lines 5-10) but does not provide any working examples or guidance as such.

6. the quantity of experimentation needed and the level of the skill in the art: and

Because neither the prior art nor the current application provide sufficient guidance to one of even ordinary skill in the art as to the prevention of vaginal atrophy and vaginal pain during sexual intercourse, the quantity of experimentation for such a claim is considered to be undue and thus, not enabled.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-2, 6, 11-12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,031,002 (Wysor *et al.*)(cited in Applicants' 1449) teaches treatment methods for female sexual dysfunctions. Wysor *et al.* teaches methods for enhancing sexuality in a female having a clitoris comprising topically administering VIP to the clitoris and surrounding areas. The administration can be via ointment, gel, foam or spray, and liposome (see column 3 lines 45-64; column 4 lines 42-67; column 5 lines 3-8).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-2, 6-11, 12-15 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ottensen *et al.* 1987 (Peptides, Vol. 8, No. 5, pages 797-800). Ottensen *et al.* teaches administration of vasoactive intestinal peptide (VIP) via intravenous or subepithelial injection in the vaginal wall for increased vaginal blood flow and induced vaginal fluid production, which is associated with local physiological changes observed during sexual arousal: genital vasodilatation and increases in vaginal lubrication. The result-effective adjustment of particular conventional working conditions (e.g., choosing other commonly employed modes of administration and/or inclusion of other well known sexual dysfunctional agents therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

9. Claims 1-15 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wysor *et al.* (cited above) and Ottesen *et al.* 1985 (Regulatory Peptides, Vol. 11, pages 83-92). Wysor *et al.* teaches the topical application of VIP to the clitoris and surrounding tissues via different delivery systems, but does not teach the combinatorial use of VIP with steroids in topical use for the treatment of female sexual dysfunction. Ottesen *et al.* teach the use of steroids in affecting VIP (page 83). Ottesen *et al.* teaches that the sensitivity effects for VIP was significantly higher in the presence of progesterone and oestrogen. Furthermore, Ottesen *et al.*

teaches that the "sensitivity for and potency of VIP on the relaxation of uterine muscle was significantly higher" when the steroids were used.

The combination of Wysor *et al.* and Ottensen *et al.* would be obvious to of ordinary skill in the art wherein Ottensen *et al.* teaches the beneficial effects of using steroids in the area of the vagina for increased sensitivity and potency of VIP, and wherein Wysor *et al.* teaches the beneficial effects of topically applying VIP to the vaginal area for increased sexual response. The claimed invention wishes to use the combination for the very reason for which the combination would be obvious and that is to increase the responsiveness of the vaginal area regarding sexual dysfunction in females. The result-effective adjustment of particular conventional working conditions (e.g., times of administration, amounts, delivery devices, etc.) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claim Objections

10. **Claim 1 is objected to because of the following informalities:** claim 1 at line 6 requires the insertion of the word "of" between "consisting" and "vasoactive". Appropriate correction is required.

Art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure (these reference are cited in applicants' Information Disclosure Statement).

Levin, R.J. 1991. VIP, Vagina, Clitoral and Periurethral Glans – an Update on Human Female Genital Arousal, Exp. Clin. Endrocrinol. Vol. 98, No. 2, pages 61-69: teaches treatment of female dysfunctions of arousal by subepithelial injection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism
25 March 2004

CHRISTOPHER R. TATE
PRIMARY EXAMINER